

SHIELD Scientific B.V.

Dr. Willem Dreeslaan 1,
6721 ND Bennekom,
The Netherlands.

It is certified that the manufacturer's technical file and the PPE product detailed on page 2 have been assessed and found to be in accordance with

EC Directive 89/686/EEC

EC Type-examination

This certificate is valid from 27 November 2017 until 27 November 2022
Issue 1. Certified since 27 November 2017

Authorised by

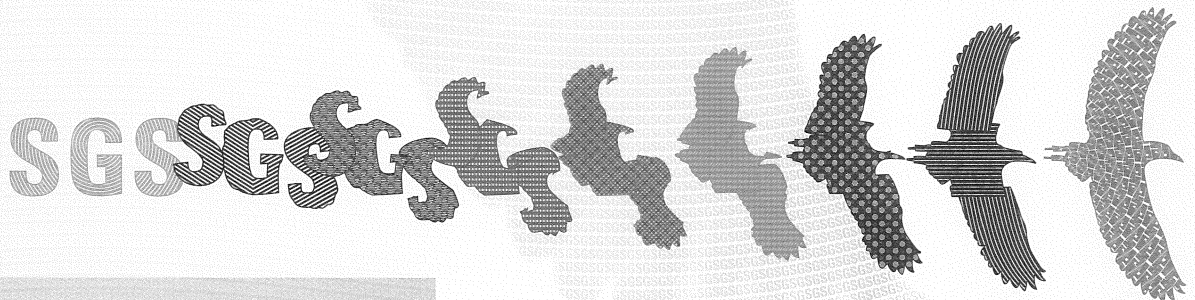
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SHIELD Scientific B.V.

EC Directive 89/686/EEC

EC Type-examination

Issue 1

PPE Product

- a) duoSHIELD™ PFT Nitrile 240 ,disposable powder-free white nitrile gloves, ambidextrous, with beaded cuff and textured fingertips, non-sterile, which are available in five nominal hand sizes: 6/XS(product code: 65 8121), 7/S (65 8122), 8/M (65 8123), 9/L (65 8124) & 10/XL (65 8125);
- b) duoSHIELD™ PFT Nitrile 290 ,disposable powder-free white nitrile gloves, ambidextrous, with beaded cuff and textured fingertips, non-sterile, which are available in five nominal hand sizes: 6/XS(product code: 65 8141), 7/S (65 8142), 8/M (65 8143), 9/L (65 8144) & 10/XL (65 81245).

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to be in accordance with the requirements of Council Directive 89/686/EEC. When examined the PPE satisfied the requirements in the relevant harmonized standard:

EN 374-1:2016 (Protective gloves against chemicals and micro-organisms)

Type C gloves: permeation performance \geq level 2 with reagents: K & T;

EN 374-5:2016 (Protective gloves against chemicals and micro-organisms)

gloves protecting against virus, bacteria and fungi (EN 374-2:2014 performance level 3).

The manufacturer's information notice (duoSHIELD™ PFT Nitrile 240 & PFT Nitrile 290 gloves dispenser boxes), in English, has been inspected and found to have addressed all of the relevant requirements of the standard. However, the detailed content of the information notice is the responsibility of the manufacturer, as are translations into other languages.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 11 of the Directive are implemented and maintained while the model is in production.

Certification is based on technical file 65 812X & 65 814X version 17.1,

dated 24 -09-2017

SGS Reference Number GB/PP 237055

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EC Declaration of Conformity
for Medical Devices and Personal
Protective Equipment

Revision: 01
Revision Date: 27.11.17
Originator: J.F. Robles

Product: duoSHIELD™ PFT Nitrile 240 Powder Free Ambidextrous Non-Sterile 24 cm Nitrile Gloves with Textured Fingertips

Product Codes:	SHIELD Scientific codes	Size
	65 8121	6/XS
	65 8122	7/S
	65 8123	8/M
	65 8124	9/L
	65 8125	10/XL

Classification: Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

The manufacturer established in the Community:

**SHIELD Scientific B.V.,
Dr Willem Dreeslaan 1,
6721 ND BENNEKOM,
The Netherlands**

declares that the new Medical Device and PPE (Product Codes as mentioned above) described hereafter:

duoSHIELD™ PFT Nitrile 240

is in conformity with the provisions of Council Directive 93/42/EEC and with the national standards transposing harmonized standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009. It is self-certified as a Medical Device Class 1.

is in conformity with the provisions of Council Directive 89/686/EEC and with the harmonized standards EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015 (supersedes EN 374-3: 2003), EN 374-4:2013, EN ISO 374-5:2016 and EN 420:2003 + A1:2009. This device is identical to the PPE, which is the subject of EC certificate of conformity no. GB17/873537 issued by the Notified Body:

**SGS UK Ltd (Notified Body No: 0120),
Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA,
United Kingdom**

This device is subject to the procedure set out in Article 11 point B of Directive 89/686/EEC under the supervision of the Notified Body:

**SGS UK Ltd (Notified Body No: 0120),
Unit 202B Worle Parkway, Weston-super-Mare, BS22 6WA,
United Kingdom**

Done at Bennekom on 27th November 2017.

J.F. ROBLES
General Manager



Validity of this Declaration: 27th November 2017 until 27th November 2022.

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